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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/502,698	02/11/2000	Shin-Ichi Funahashi	06501-056001	5541
26161	7590	01/14/2005	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			MERTZ, PREMA MARIA	
			ART UNIT	PAPER NUMBER
			1646	
DATE MAILED: 01/14/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/502,698

Applicant(s)

FUNAHASHI ET AL.

Examiner

Prema M Mertz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3 and 9-37 is/are pending in the application.
- 4a) Of the above claim(s) 9-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3, 35-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/21/2004 has been entered.
2. Claims 1-2, 4-5 have been canceled. Claims 9-34 have been withdrawn from consideration as drawn to a non-elected invention. Previously presented claims 3, 35-37 are pending in the instant application and are under consideration by the Examiner.
3. Receipt of applicant's arguments and amendments filed on 10/21/2004 is acknowledged.
4. Applicant's arguments filed on 4/29/04 have been fully considered and were non-persuasive. The remaining issues are stated below.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § § 101/112, first paragraph

6. Claims 3, 35-37 are rejected under 35 U.S.C. 101.

This rejection is maintained for reasons of record set forth at pages 3-5 of the previous Office action (4/18/03) and pages 2-3 of the Office action (9/22/03).

Applicants argue that the polypeptides at issue can be used for generating antibodies to be employed in detecting liver cells and lung cancer tissues, and that this use is specific, substantial and credible and have cited Example 12 of the USPTO Utility

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Guidelines Training material in this regard. Furthermore, Applicants argue that post-filing date evidence discloses that the claimed polypeptides bind to 5-HT_{2C} receptors which are known to be involved in neural transmission and have cited the Ullmer et al publication demonstrating a 454 amino acid polypeptide fragment that is 98% identical to a portion of SEQ ID NO:1 and 2 that binds to the serotonin 5-HT_{2C} receptor. However, contrary to Applicants arguments, it is clear from the instant specification that the instantly claimed protein is what is termed an "orphan protein" in the art. As shown in Figure 2 of the instant specification, there is only 98% homology between a "portion" of the instant protein (from amino acid 921-1373) and the receptor protein of Ullmer et al. However, the Ullmer et al publication discloses that the MUPP1 protein which is a member of the PDZ protein family interacts with the C-terminus of the 5-HT_{2C} receptors i.e. the PDZ domain protein MUPP1 is a scaffolding protein that interacts with the 5-HT_{2C} receptor. This disclosure in the post-filing reference was not disclosed in the present application as filed.

Applicant has also traversed this rejection on the premise that a claimed protein can be employed in identifying compounds that agonize or antagonize activity of 5-HT_{2C} receptor, which utility Applicants argue is a credible, specific and substantial utility. Applicants argue that the methods for screening for compounds and for generating antibodies is a specific, substantial and credible utility. However, the employment of a protein of the instant invention, in identifying compounds that agonize or antagonize activity of the 5-HT_{2C} receptor is not a credible, substantial or specific utility. To grant Applicants a patent encompassing an isolated protein of as yet undetermined biological significance would be to grant Applicant a monopoly "the metes and bounds" of which

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"are not capable of precise delineation". That monopoly "may engross a vast, unknown, and perhaps unknowable area" and "confer power to block off whole areas of scientific development, without compensating benefit to the public" *Brenner v. Manson, Ibid*). To grant Applicant a patent on the claimed polypeptide based solely upon an assertion that a portion of the instant protein has 98% homology to the 454 amino acid fragment of Ullmer et al, is clearly prohibited by this judicial precedent since the compensation to the public is not commensurate with the monopoly granted. The instant protein has no demonstrated function.

Applicants also argue that the claimed polypeptide has a specific and substantial utility because it can be used in identification of certain tissues including liver and lung tumor cells and this supports the utility of the antibodies for detection of either liver cells or lung cancer cells. However, the employment of the claimed polypeptide in such a method is not a substantial or specific utility, because the instant polypeptide has not been shown to be differentially expressed in normal and lung tumors. Applicants have failed to show differential expression of the instant nucleic acid in normal lung tissue and in lung tumor tissue. Applicant is not being required to identify a ligand for protein, **and** a physiological process mediated thereby **and** a disease or disorder for which that protein is a marker. Applicant is only required to identify **one** substantial credible utility and, as stated in the previous office action, the employment of this protein only as the subject of further research does not satisfy the utility requirement of 35 U.S.C. § 101 because the courts have interpreted this statute as requiring an invention to have "substantial utility" "where specific benefit exists in currently available form". The employment of a protein of the instant invention, as a tissue specific marker is not a substantial or specific utility.

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All human proteins can invariably be classified into two categories, those which are expressed in a tissue or developmentally specific manner and those which are expressed ubiquitously. It can be alleged that any protein which is expressed in a tissue specific manner can be employed to detect the tissue in which it is expressed in a sample. Alternately, a human protein which is expressed ubiquitously can be employed to detect the presence of any human tissue in a sample. Such utilities are analogous to the assertion that a particular protein can be employed as a molecular weight marker, which is neither a specific or substantial utility.

The examiner must simply provide sound reasoning in support of a conclusion that an element is lacking from a specification, and this has been done. In the instant case, it is the responsibility of Applicant to disclose a specific utility for the claimed invention and factually unsupported assertions like those presented i.e. in detection of lung tumors, are not specific utilities on their face that they need not be "proven" wrong.

The following is an excerpt from M.P.E.P. 2138.05:

Utility for the invention must be known at the time of the reduction to practice. *Wiesner v. Weigert*, 212 USPQ 721, 726 (CCPA 1981) (except for plant and design inventions); *Azar v. Burns*, 188 USPQ 601, 604 (Bd. Pat. Inter. 1975) (a composition and a method cannot be actually reduced to practice unless the composition and the product produced by the method have a practical utility); *Ciric v. Flanigen*, 185 USPQ 103, 105 - 6 (CCPA 1975) ("when a count does not recite any particular utility, evidence establishing a substantial utility for any purpose is sufficient to prove a reduction to practice"; "the demonstrated similarity of ion exchange and adsorptive properties between the newly discovered zeolites and known crystalline zeolites ... have established utility for the zeolites of the count"); *Engelhardt v. Judd*, 151 USPQ 732, 735 (CCPA 1966) (When considering an actual reduction to practice as a bar to patentability for claims to compounds, it is sufficient to successfully demonstrate utility of the compounds in animals for somewhat different pharmaceutical purposes than those asserted in the specification for

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humans.); *Rey - Bellet v. Engelhardt*, 181 USPQ 453, 455 (CCPA 1974) (Two categories of tests on laboratory animals have been considered adequate to show utility and reduction to practice: first, tests carried out to prove utility in humans where there is a satisfactory correlation between humans and animals, and second, tests carried out to prove utility for treating animals.).

A PROBABLE UTILITY MAY NOT BE SUFFICIENT TO ESTABLISH UTILITY

A probable utility does not establish a practical utility, which is established by actual testing or where the utility can be "foretold with certainty." *Bindra v. Kelly*, 206 USPQ 570, 575 (Bd. Pat. Inter. 1979) (Reduction to practice was not established for an intermediate useful in the preparation of a second intermediate with a known utility in the preparation of a pharmaceutical. The record established there was a high degree of probability of a successful preparation because one skilled in the art may have been motivated, in the sense of 35 U.S.C. 103, to prepare the second intermediate from the first intermediate. However, a strong probability of utility is not sufficient to establish practical utility.); *Wu v. Jucker*, 167 USPQ 467, 472 (Bd. Pat. Inter. 1968) (screening test where there was an indication of possible utility is insufficient to establish practical utility). But see *Nelson v. Bowler*, 206 USPQ 881, 885 (CCPA 1980) (Relevant evidence is judged as a whole for its persuasiveness in linking observed properties to suggested uses. Reasonable correlation between the two is sufficient for an actual reduction to practice)."

Furthermore, use of the protein to raise antibodies is analogous to the assertion that a particular DNA can be employed as a molecular weight marker, which is neither a specific or substantial utility.

There has to be physiological significance for the polypeptide disclosed in the specification. This requirement is analogous to basic scientific characterization, however, in the instant case no substantial benefit for the claimed protein is currently disclosed, but an exploratory significance. In conclusion, Applicants arguments with respect to utility of the instant polypeptide, are found to be non-persuasive. Contrary to Applicants arguments, the instant specification does not disclose a single credible,

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specific or substantial utility for the instant polypeptide. The initial burden to demonstrate or present such is on Applicants.

Claims 3, 35-37 also remain rejected under 35 U.S.C. 112, first paragraph, as failing to adequately teach how to use the instant invention. Claims 3, 35-37 stand rejected under 35 U.S.C. § 112, first paragraph, because the instant specification does not teach how to use the invention for those reasons of record in pages 3-5 of the previous Office action (4/18/03) and pages 2-3 of the Office action (9/22/03).

Claim rejections-35 USC § 112, second paragraph

7. Claims 3, 35-37 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is unclear because it recites “comprising the sequence of SEQ ID NO:1” rather than “comprising the amino acid sequence of SEQ ID NO:1”.

Claim 35 is unclear because it recites “comprising SEQ ID NO:2” rather than “comprising the amino acid sequence of SEQ ID NO:2”.

Claim 36 is unclear because it recites “consists of SEQ ID NO:2” rather than “consists of the amino acid sequence of SEQ ID NO:1”.

Claim 37 is unclear because it recites “consists of SEQ ID NO:2” rather than “consists of the amino acid sequence of SEQ ID NO:2”.

Conclusion

No claim is allowed.

Advisory Information

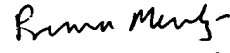
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
January 11, 2005